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January 25, 2013

In re Merck & Co., Inc. Securities, Derivative & ERISA Litigation
The Consolidated Securities Action, No. 05-CV-02367

Dear Magistrate Judge Waldor:

We represent Defendants (other than Dr. Scolnick) in the above-captioned action and respectfully submit this letter in response to Plaintiffs' January 23, 2013 letter to this Court (the "January 23 Letter") in advance of the January 28, 2013 status conference.

In their January 23 Letter, Plaintiffs seek to require Defendants to (1) review tens of thousands of likely privileged documents that post-date the withdrawal of Vioxx from the files of Kenneth Frazier, who until 2007 was Merck's General Counsel with primary responsibility for Merck's defense strategy in all Vioxx-related litigation, including this Consolidated Action (Jan. 23 Ltr. at 1-2); (2) conduct unnecessary "exact phrase" searches for draft public statements, even though Defendants have already undertaken an extensive search for such documents from the files of any Merck employees or departments likely to have them and have already produced myriad responsive documents (*id.* at 2); (3) provide further responses to certain interrogatories to which Defendants, in good faith and through substantial effort, have already provided over 200 pages of responses (*id.* at 2-3); and (4) produce certain documents provided by Merck to the Department of Justice pursuant to a limited waiver agreement, which Defendants have already provided to Plaintiffs (*id.* at 4). None of these issues necessitates relief from the Court.

DEFENDANTS' PRODUCTION TO DATE

Plaintiffs' demands arise in the context of a massive discovery effort by Merck. To date, Merck has produced more than 29 million pages of documents, including tens of millions of pages of documents from thousands of other Vioxx-related cases filed across the country in the wake of Merck's voluntary withdrawal of Vioxx on September 30, 2004. Merck's production includes virtually all of the discovery underlying those cases, including hundreds of thousands (if not millions) of pages of study data and analysis, hundreds of deposition transcripts

and exhibits, and full trial transcripts of 18 products liability cases concerning the cardiovascular safety of Vioxx that were tried to verdict. Merck's production also includes over 5 million pages produced over the past 14 months—a production which is ongoing based on Plaintiffs' continued requests. This monumental production contains documents collected from thousands of current and former Merck employees, produced from hundreds of custodians, and spans a time period of more than a decade, from the mid-1990s through mid-2008.

DEFENDANTS' RESPONSE TO THE ISSUES RAISED IN PLAINTIFFS' JANUARY 23 LETTER

I. Plaintiffs Are Not Entitled to Post-September 29, 2004 Documents From the Files of Kenneth Frazier.

Defendants have already agreed to produce, and are in the process of producing, responsive, non-privileged documents from the files of Kenneth Frazier from January 1, 1998, through the proposed class period (May 21, 1999 through September 29, 2004) and for three months beyond, through December 31, 2004. Plaintiffs now seek to require Defendants to review for responsiveness tens of thousands of additional documents post-dating September 29, 2004, from Mr. Frazier's files. In his role as Merck's General Counsel from 1999 through 2007, Mr. Frazier led the Company's legal strategy in defending against Vioxx-related litigation and proceedings, which grew to tens of thousands of lawsuits following the Company's withdrawal of Vioxx on September 30, 2004. As such, the vast majority of Mr. Frazier's responsive documents created after the end of the proposed class period will be privileged legal advice and/or protected work product created in anticipation of litigation. Moreover, the burden of reviewing these likely privileged documents would be immense. Mr. Frazier's custodial file for the time period from September 30, 2004 through June 30, 2008 contains tens of thousands of documents—more than the combined total documents for *eight* other custodians that Defendants have agreed to review for this post-withdrawal time period. Indeed, to evaluate this burden, Defendants have reviewed a sample of Mr. Frazier's documents from the period of September 30, 2004 through mid-2006 and found that only 2% were responsive—without undertaking the additional time to review responsive documents for privilege. Given this very low responsiveness rate, coupled with the very high likelihood that any responsive documents would nonetheless be privileged, it is clear that the burden of reviewing Mr. Frazier's post-withdrawal documents would far outweigh any potential benefit, *see* Fed. R. Civ. P. 26(b)(2)(C)(iii), particularly in light of the massive amount of other discovery Plaintiffs already have, *see Jaffe Pension Plan v. Household Int'l, Inc.*, No. 02 C 5893, 2006 WL 3445742, at *5 (N.D. Ill. Nov. 22, 2006) (volume of prior discovery, including discovery of post-class period documents, "is a useful reference for estimating the burden").

Plaintiffs nonetheless argue that Defendants should be forced to undertake this burdensome review because there may exist a handful of non-privileged documents regarding Mr. Frazier's alleged role as "Senior Vice President in Merck's Public Affairs division, a title he held since 1999." (Pls.' Jan. 23 Ltr. at 1.) This does not justify a review of Mr. Frazier's post-September 29, 2004 files. *First*, as the Court has already ordered, Plaintiffs may only seek post-September 29, 2004 documents that are relevant to the issue of scienter. (*See* Sept. 26, 2012 Order at 3-4, ECF No. 398.) Any documents in Mr. Frazier's files from this time period demonstrating any Defendant's alleged state of mind during the proposed class period would

almost certainly be privileged or work product documents obtained in his capacity as Merck's chief legal advisor overseeing the Vioxx litigation—not in his capacity in any public affairs role.

Second, to the extent Mr. Frazier's documents relating to any role in public affairs are relevant at all, they would be relevant only for the period of time when Vioxx was on the market and the alleged misstatements were made—*i.e.*, May 21, 1999 through September 29, 2004. Indeed, Plaintiffs' own letter claims that the reason Mr. Frazier is relevant is due to his "involvement in the marketing and promotion of Vioxx, and his communications with top Merck scientists concerning Vioxx's cardiovascular safety"—acknowledging that they already have "such documents in Defendants' current production." (Pls.' Jan. 23 Ltr. at 2.) Indeed, Defendants have already agreed to review Mr. Frazier's files through December 31, 2004—several months after Vioxx was voluntarily withdrawn from the market. We respectfully submit that nothing more should be required for Mr. Frazier's files.

II. Merck Should Not Be Required To Conduct Independent Searches For "Exact Phrases" in Merck's Draft Public Statements.

Defendants have agreed to produce all non-privileged draft public statements by Merck regarding Vioxx during the proposed class period. To locate such documents, Defendants have conducted, and are continuing to conduct, a reasonable search of the files of various Merck current and former employees, as well as the files of relevant Merck departments, likely to have such documents. Defendants' reasonable search treats any portion of draft public statements to be responsive to Plaintiffs' request for such documents. In light of this broad review, the use of additional "exact phrase" searches that Plaintiffs purport to require would be ineffective, unnecessary, and (at best) duplicative.

The sole justification that Plaintiffs offer in support of "exact phrase" searches is that it they are purportedly "critical to ensure" a complete production. (Pls.' Jan. 23 Ltr. at 2.) This argument, however, presupposes that an "exact phrase" that might be used to search for a particular document would be the same across all versions. Words used in a draft, however, are by definition subject to change. Thus, what Plaintiffs attempt to frame as a simple application of search terms is instead an iterative process that would in many cases require search terms to be altered as the draft document evolves—or might even result in Defendants missing documents that do not use the "exact phrase." Thus, far from "ensuring" that all draft public statements are located, the use of "exact phrase" searches might inappropriately limit Defendants' search. By contrast, Defendants' ongoing manual review of the appropriate custodians' and department files best and most efficiently enables Defendants to review all drafts of public statements—whatever phrases they use as they evolve over time—and will thus ensure that Defendants have produced all responsive, non-privileged drafts of such statements.

III. Defendants' Responses To Plaintiffs' Interrogatories Are More Than Adequate.

Plaintiffs' First Set of Interrogatories purports to require Defendants to review the more than 29 million pages of documents already produced in this case and provide Plaintiffs with narrative summaries of nearly every formal or informal analysis of Vioxx cardiovascular safety data ever conducted. Despite the obvious burden of such discovery, Defendants in good faith, and with significant effort, provided Plaintiffs with a 220-page, detailed response,

including a thirteen-page appendix identifying relevant Bates ranges for the reports and publications summarizing numerous clinical trials and meta-analyses. (*See* Defs.' Ex. A.) Defendants' response amply satisfies the requirements of Federal Rule of Civil Procedure 33. *See* Fed. R. Civ. P. 33(d) ("If the answer to an interrogatory may be determined by examining . . . a party's business records . . . , and if the burden of deriving or ascertaining the answer will be substantially the same for either party, the responding party may answer by . . . specifying the records that must be reviewed, in sufficient detail to enable the interrogating party to locate and identify them as readily as the responding party could.").

Unsatisfied with this mountain of information, Plaintiffs now demand that Defendants review, identify within the production and summarize for Plaintiffs:

- "all statisticians, statistical programmers or data coordinators" who ever did any work in connection with thirteen clinical trials and over a half dozen additional meta-analyses (Pls.' Jan. 23 Ltr. at 2);
- all data from numerous clinical trials produced in SAS software format (*id.*);
- all "documents reflecting" meta-analyses of trials involving osteoarthritis and rheumatoid arthritis, regardless of whether these analyses were formally conducted by Merck or were mere "back of the envelope" looks at data points from two or more trials conducted without any formal documentation (*id.* at 3);
- the name of every person "who decided on Merck's description of . . . adverse cardiovascular events, regardless of whether these "deci[sions]" were formal adjudications or were simply logged by investigators (*id.*); and
- the "definitions" used by Merck to categorize "cardiovascular events in Vioxx trials," regardless of whether they are based on Merck's definition of formal adjudication or are based on some unspecified informal definition (*id.* at 2-3).

With respect to the first category (Interrogatory 2), as we have informed Plaintiffs, Defendants are not aware of any pre-existing documents identifying each and every statistician, statistical programmer or data coordinator who may ever have done anything at any time to assist on any of these clinical trials. Nevertheless, in good faith, Defendants identified by Bates number the Clinical Study Report for each study, which identifies the key personnel for the particular study. Because Plaintiffs' "burden of deriving or ascertaining" any additional information in response to their interrogatory "will be substantially the same" as for Defendants, *see* Fed. R. Civ. P. 33(d), Defendants' response to Interrogatory 2 is more than sufficient.

Plaintiffs' second category (Interrogatory 3), rests on the incorrect premise that all data from each clinical trials exist in the SAS software format. Defendants have produced the entire Vioxx Clinical Trial System database, which is the official database of Vioxx clinical trial information. While Defendants remain willing to entertain specific questions about specific data, Plaintiffs' request is inappropriate and impossible to comply with.

With respect to the final three categories (Interrogatories 4, 5, 6, 7, and 8), Defendants have identified the Bates ranges of the documents in which the formal meta-analyses and adjudications can be found. All such meta-analyses were produced to Plaintiffs long ago, as were the identities of and definitions used by the outside adjudicators who were charged with formally and independently assessing adverse events reported by trial investigators. With

respect to "informal" analyses, Merck scientists constantly reviewed study data relating to Vioxx over a period of many years. Defendants are in no better position than Plaintiffs to know every instance when any scientist reviewed data. Defendants have produced many millions of pages of Vioxx science-related documents and voluminous deposition testimony, including specifically on the adverse experience reporting process, and made a good faith effort to provide Plaintiffs with the Bates ranges where documents containing information they seek might be found. Such good faith responses to Interrogatories 4, 5, 6, 7, and 8 are more than sufficient under Rule 33(d).

IV. Defendants Have Complied With This Court's Order Regarding The Production of Certain Documents that Merck Provided to the United States Attorneys' Office.

On December 22, 2012 Defendants provided to Plaintiffs a production of the documents that were produced to the United States Attorney's Office for the District of Massachusetts ("USAO"). (*See* Pls.' Ex. G.) In advance of that production, and as Plaintiffs were aware, Defendants reviewed those documents to determine which documents were "otherwise responsive to Plaintiffs' Requests," in accordance with Plaintiffs' motion and the Court's October 5 Letter Opinion. (Ltr. Op. at 2, ECF No. 405 (observing that Plaintiffs seek "documents that [Defendants] previously produced to the government *and which are otherwise responsive to Plaintiffs' Requests*." (citing Pls.' May 25, 2012 Ltr. to M.J. Shipp at 5-9) (emphasis added)); *accord* Pls.' May 25, 2012 Ltr. to M.J. Shipp at 6.)

Following an inquiry by Plaintiffs regarding the December 22 Production, Defendants re-reviewed the non-responsive documents to ensure that all responsive documents had been produced as Defendants intended. In doing so, Defendants discovered an error in the digitized version of the document set (created many years ago), which resulted in certain documents becoming disassociated in the digitized review set from their attachments. Immediately upon discovering this, Defendants obtained from Merck's counsel in the USAO investigation an original set of the paper production as made to the USAO, and commenced a manual re-review of the entire set of those documents. As Plaintiffs note, Defendants' counsel also informed Plaintiffs' counsel that we were in the process of re-reviewing the full set of documents for responsiveness. (Pls.' Jan. 23 Letter at 4.) Based on the manual re-review, Defendants have made a replacement production to Plaintiffs of all documents responsive to Plaintiffs' Requests. To avoid any confusion, Defendants have made this new production in hard copy (*i.e.*, paper format), the format in which it was produced to the USAO.

To the extent Plaintiffs seek information regarding the documents from this manual review that were non-responsive to Plaintiffs' Requests, Defendants submit that such information is protected by Federal Rule of Criminal Procedure 6(e) because it would necessarily "reveal what occurred before the grand jury." (Ltr. Op. at 6-7, ECF No. 405 (citing *United States v. Jackson*, No. 00-138, 2009 WL 1578939, at *2-3 (D.N.J. June 4, 2009); *In re Grand Jury Matter*, 697 F.2d 511, 512 (3d Cir. 1982)).)[1]

[1] Plaintiffs also complain that Defendants had not responded to their letter of January 11, 2013. (Pls.' Jan. 23 Ltr. at 4.) Defendants responded to that letter on January 25, 2013, as we

Respectfully submitted,

Karin A. DeMasi

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informed Plaintiffs we would. (*See* Pls.' Ex. K.) Defendants do not understand any of the issues in those letters to require the Court's attention.

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